

REMARKS

Reconsideration of the rejections set forth in the Office Action dated October 01, 2007 is respectfully requested in view of the foregoing amendments and following remarks. This amendment is accompanied by a separate petition for a two-month extension of time to extend the date for response to March 1, 2008, which falls on a Saturday and therefore continues to Monday, March 3, 2008.

I. **Amendments**

Claims 1, 3, 17, 18, 49, 50, 51, 54, 55, 97, 105, 106, 119, 120, 145, 146, 147, 150, and 151 are amended.

Claims 152-154 are new.

Claims 1, 97, and 105 are amended to recite a *therapeutic* drug. Support for the added language can be found, for example, at page 18, lines 28-30 and page 19, lines 25-27.

Claims 1, 97, and 105 are amended to recite a *solid matrix comprising a hydrophilic polymer that swells unrestricted dimensionally*. Support for the added language can be found, for example, at page 15, lines 21-25.

Claims 1, 97, and 105 are amended to remove language reciting that the solid matrix is of a *size large enough* to be retained in the stomach.

Claims 1, 97, and 105 are amended to recite that the fed mode inducing agent is selected from alkali and alkaline earth metal docusates. Support for the amendment can be found, for example, at page 5, line 16; page 9, lines 1-8; and page 24 (Table 1).

Claims 3 and 106 have been amended to correct an obvious word-processing error.

Claims 17, 18, 119, and 120 are amended to update their dependencies and to delete unnecessary language.

Claims 49-51 have been amended to conform to the language of newly amended claim 1 from which each claim indirectly depends.

Claims 54 and 55 have been amended to provide proper antecedent basis for the phase "water-soluble matrix".

Claims 145-147 have been amended to conform to the language of newly amended claim 105 from which each claim indirectly depends.

Claims 150 and 151 have been amended to delete unnecessary language.

Claims 152 and 154 are new. These claims are directed to compositions in which the fed mode inducing agent is sodium docusate. Support for this language is found in the specification, for example, at page 9, line 5.

Claims 5-9, 14-16, 19-26, 32-34, 99-104, 109-118, and 121-142 are canceled without prejudice or disclaimer. Applicants reserve the right to pursue claims drawn to the canceled subject matter in one or more future applications.

Following entry of the foregoing amendments, claims 1-4, 17, 18, 47-55, 97-98, 105-108, 119, 120, and 143-154 will be pending in the application.

No new matter has been added by way of the amendments herein.

II. Objections to the claims

Claim 99 was objected to in view of a typographical error.

Claim 99 has been canceled.

Withdrawal of the objection is therefore respectfully requested.

III. Rejections under 35 U.S.C. § 112, second paragraph (indefiniteness)

A. Claims 8, 9, 17, 18, 21, 22, 25, 26, 33, 34, 102-104, 114, 115, 119, 120, 128, 129, 132, 133, 137, 138, 141, and 142 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite for reciting the term "from about," which it is alleged is not defined by the claim or supported by a standard in the specification.

B. Claims 1-9, 14-26, 32-34, 47-55, and 97-151 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite for reciting the phrase "size sufficiently large," which it is asserted is not defined by the claim or supported by a standard in the specification.

C. Claim 99 stands rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite for language relating to potency.

Response

A. *From about*

The term "from" has been deleted from claims 17, 18 and 119 and 120 which is believed to address the rejection. Claims 8, 9, 21, 22, 25, 26, 33, 34, 102, 104, 128, 129, 132, 133, 137, 138, 141, and 142 have been canceled, obviating the rejections with respect to these claims.

In view of these amendments, withdrawal of the rejection is respectfully requested.

B. *Size sufficiently large*¹

The term "size large enough" has been deleted from independent claims 1, 97, and 105, from which claims 2-4, 17, 18, 47-55, 98, 106-108, 119, 120, and 143-155 depend. The amendment is believed to address the rejection.

Claims 5-9, 14-16, 19-26, 32-34, 100-104, 111-118, 121-142 have been canceled, obviating the rejections with respect to these claims.

Accordingly, withdrawal of the rejection is respectfully requested.

¹ Note that in dependent claims 1, 97, and 105 used the language "size large enough," rather than "size sufficiently large." Applicants have nonetheless addressed the spirit of the rejection.

C. *Potency*

Claim 99 has been canceled. Accordingly, withdrawal of the rejection is respectfully requested.

In view of the foregoing, it is submitted that the claims meet the standards of 35 U.S.C. § 112, second paragraph.

IV. Rejections under 35 U.S.C. § 102

Claims 1-6, 14-18, 47, 48, 105-107, 143, and 144 were rejected under 35 U.S.C. § 102(b) as allegedly anticipated by MacKenzie *et al.* (1990) *Fundamental and Applied Toxicology*.

Claims 1-6, 14-18, 47, 48, 105-107, 143, and 144 were rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Kais *et al.* (USPN 5,516,524).

These rejections are traversed in view of the foregoing amendments and following remarks.

A. Summaries of the Cited Documents

The teachings of MacKenzie *et al.* and Kais *et al.* are summarized in Applicants' Response dated January 29, 2007 and in the Office Action dated October 1, 2007.

B. Analysis

The standard for lack of novelty, that is, for anticipation, is one of strict identity. To anticipate a claim for a patent, a single prior source must contain all its essential elements. M.P.E.P. § 2131.

The present claims require, *inter alia*, a therapeutic drug retained in a solid matrix comprising a hydrophilic polymer that swells unrestricted dimensionally in a manner causing retention of the solid matrix in the stomach during the fed mode and release of said drug.

Neither MacKenzie *et al.* nor Kais *et al.* teach this claimed feature of a therapeutic drug retained in a solid matrix comprising a hydrophilic polymer that swells

unrestricted dimensionally in a manner causing retention of the solid matrix in the stomach during the fed mode and release of said drug.

As none of the references teaches each and every limitation of the claims, none of the references anticipates the pending claims. Withdrawal of the rejection is respectfully requested.

V. Rejection under 35 U.S.C. § 103

Claims 1-6, 14-18, 32-34, 47, 55, 97-110, 112, 116-124, 130, and 143-151 stand rejected under 35 U.S.C. § 103 as allegedly anticipated by Wong *et al.* (USPN 6,120,803) taken with MacKenzie *et al.* (1990) *Fundamental and Applied Toxicology* in view of Hagen *et al.* (2002) *Proc. Nat'l. Acad. Sci. USA* 19:1870-75; Shaffer *et al.* (1987) *Am. Soc. Clin. Nutrition* 45:744-47; and Pupovac *et al.* (2002) *J. Nutrition* 132:2775-80.

Analysis

A. Wong *et al.*

The teachings of Wong *et al.* are summarized in the Office Action dated October 1, 2007. However, a feature of the drug delivery device of Wong *et al.* not mentioned in the Office Action is that the device "should exhibit a combination of flexibility and rigidity" (col. 4, line 65 – col. 5, line 1). In particular, the device of the Wong *et al.* includes "a rigid or semi-rigid section" in the form of insoluble material (col. 5, lines 17-21, which is readily shown in Figs. 1B, 2, 3A, 3B, 4A, 4B, 4C, 4D, 5, 7, and 6.

In contrast to the teaching of Wong *et al.*, independent claims 1, 97, and 105 all require *a therapeutic drug retained in a solid matrix comprising a hydrophilic polymer that swells unrestricted dimensionally*. Wong *et al.* fail to teach or suggest a dosage form having these characteristics. Moreover, Wong *et al.* explicitly teach against a dosage form that *swells unrestricted dimensionally*.

In addition, Wong *et al.* teach the administration of arginine as a fed mode inducing agent, while the pending claims require alkali and alkaline earth metal

docusates. Wong *et al.* fail to teach or suggest a dosage form comprising alkali and alkaline earth metal docusates.

B. Secondary references

MacKenizie *et al.*, Hagen *et al.*, Shaffer *et al.*, and Pupovac *et al.* are summarized in the Office Action dated October 1, 2007. As discussed above, MacKenizie *et al.* appear to teach the administration of fed mode inducing agents. Hagen *et al.*, Shaffer *et al.*, and Pupovac *et al.* further teach the administration of α -lipoic acid, xylitol, and β -casomorphin, respectively, to affect gastric emptying.

None of the secondary references, either individually or in combination, address the defect in Wong *et al.*, with respect to failing to teach or suggest *a therapeutic drug retained in a solid matrix comprising a hydrophilic polymer that swells unrestricted dimensionally*, as required by independent claims 1, 97, and 105. The secondary references only disclose additional teachings related to the induction of the fed mode. Therefore, the secondary references fail to correct the defect in Wong *et al.*, and therefore cannot be combined with Wong *et al.* to support a prima facie case for obviousness.

Applicants further note that the present application was filed on November 2, 1999; therefore, Hagen *et al.* (2002) *Proc. Nat'l. Acad. Sci. USA* 19:1870-75 and Pupovac *et al.* (2002) *J. Nutrition* 132:2775-80 are not prior art against the pending claims and cannot be applied as prior art against the present claims.

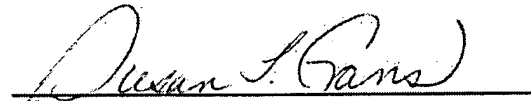
For at least the reasons discussed, it is clear than none of the cited references, individually or in combination, teaches or suggests the invention recited in claims 1, 97, and 105. Thus, the obviousness rejection is without foundation and withdrawal of the rejection is respectfully requested.

VI. Conclusion

Applicants believe the present application is fully in condition for allowance. Early notice to this effect is earnestly requested. If the Examiner has any questions or believes a telephone conference would expedite prosecution of this application, the Examiner is encouraged to call the undersigned at (650) 838-4406.

Respectfully submitted,
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